

### ***Remarks***

In view of the above amendments to the claims and the following remarks, Applicants respectfully request that all objections and rejections made in the Office Action of August 4, 2003, be reconsidered and withdrawn.

#### ***I. Status of the Claims***

In the present amendment, claims 1, 6, 13-16, 34, 35, and 54 are sought to be amended. Claims 2, 7-12, 17-33, 36-53, and 55-57 are sought to be canceled. New claim 58 is sought to be added. Upon entry of the foregoing amendment, claims 1-6, 13-16, 34, 35, 54, and 58 are pending with claims 1 and 13 being independent claims.

Support for the amendments to the claims may be found throughout the specification as filed. No new matter has been introduced.

#### ***II. Summary of the Office Action***

In the Office Action of August 4, 2003, the Examiner made one objection to the claims and five rejections of the claims.

#### ***III. Objections to the Claims***

In the Office Action at page 2, section 5, the Examiner objected to claim 4 as depending from canceled claim 2. Claim 4 has been amended to depend from claim 1. Applicants respectfully request reconsideration and withdrawal of this objection.

In the Office Action at page 2, section 6, the Examiner objected to claim 4 as having a typographical error. Applicants believe this objection was intended to be made against claim 16 as the objected-to word does not appear in claim 4. Claim 16 has been amended to correct the typographical error. Applicants respectfully request

reconsideration and withdrawal of this objection.

***IV. The Rejection of Claims 34, 35, and 54 Under 35 U.S.C. § 112, Second Paragraph Must be Withdrawn***

In the Office Action at pages 2 and 3, sections 7 and 8, the Examiner rejected claims 34, 35, and 54 under 35 U.S.C. § 112, second paragraph as being indefinite. Applicants respectfully request reconsideration and withdrawal of these rejections.

At page 3, section 8A of the Office Action, the Examiner rejected claims 34 and 35 as allegedly indefinite for the recitation of the "linear nucleic acid molecule of claim 1" when claim 1 did not contain the limitation "linear." Claim 34 has been amended to delete the limitation "linear." Applicants respectfully request reconsideration and withdrawal of this rejection.

At page 3, section 8B of the Office Action, the Examiner rejected claim 54 as allegedly indefinite for the recitation of "a nucleic acid molecule engineered to comprise all or a portion of at least two Ter-sites, one or more Ter-binding protein, one or more nucleotides, one or more DNA polymerases, one or more reverse transcriptases, one or more suitable buffers, one or more primers, instructions, and one or more terminating agents" as the Examiner alleged it was unclear how a nucleic acid could comprise proteins, buffers or instructions. Claim 54 has been amended to clarify the language. Applicants respectfully request reconsideration and withdrawal of this rejection.

***V. The Rejection of Claims 1, 3-6, 34, and 35 Under 35 U.S.C. § 102(b) as Being Anticipated by Lee et al. Must be Withdrawn***

In the Office Action at pages 3 and 4, sections 9 and 10, the Examiner rejected claims 1, 3-6, 34, and 35 under 35 U.S.C. § 102(b) as allegedly anticipated by Lee *et al.* (*J. Biol. Chem.* 267:8778-8784, 1992, hereinafter "Lee") as evidenced by Bussiere and Basita

(*Mol. Microbiology* 31(6):1611-1618, 1999). Applicants respectfully request reconsideration and withdrawal of this rejection.

A claimed invention is anticipated under 35 U.S.C. § 102 only if there is "[d]isclosure in a single piece of prior art of each and every limitation of a claimed invention." *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 20, 57 USPQ2d 1057, 1061 (Fed. Cir. 2000), citing *Electro Med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052, 32 USPQ2d 1017, 1019 (Fed. Cir. 1994). Lee does not disclose the invention as presently claimed. Accordingly, this rejection is improper and must be withdrawn.

Claim 1 is drawn to an isolated nucleic acid molecule engineered to comprise all or a portion of at least one Ter-site and comprising at least one recombination site. Claims 3-6, 34, and 35 depend, directly or indirectly, from claim 1. Thus, all the pending claims require a nucleic acid molecule engineered to comprise all or a portion of at least one Ter-site and comprising at least one recombination site.

Lee does not disclose a nucleic acid molecule as presently claimed. Since the cited art does not disclose each and every limitation of the presently claimed invention, Applicants respectfully request reconsideration and withdrawal of this rejection.

***VI. The Rejection of Claims 13 and 14 Under 35 U.S.C. § 102(a) as Being Anticipated by Neylon et al. Must be Withdrawn***

In the Office Action at pages 4 and 5, section 11, the Examiner rejected claims 13 and 14 under 35 U.S.C. § 102(a) as allegedly anticipated by Neylon *et al.* (*Biochemistry* 39:11989-11999, 2000, hereinafter "Neylon") as evidenced by Jonsson (*BioTechniques* 11(5):620-627, 1991). Applicants respectfully request reconsideration and withdrawal of this rejection.

A claimed invention is anticipated under 35 U.S.C. § 102 only if there is "[d]isclosure in a single piece of prior art of each and every limitation of a claimed invention." *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 20, 57 USPQ2d 1057, 1061 (Fed. Cir. 2000), citing *Electro Med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052, 32 USPQ2d 1017, 1019 (Fed. Cir. 1994). Neylon does not disclose the invention as presently claimed. Accordingly, this rejection is improper and must be withdrawn.

Claim 13 is drawn to a solid support comprising at least one oligonucleotide that comprises all or a portion of a Ter site and all or a portion of one or more recombination sites. Claim 14 depends from claim 13 and recites that the solid support is a non-biological material.

Applicants respectfully submit that Neylon does not disclose a solid support comprising at least one oligonucleotide that comprises all or a portion of a Ter site and all or a portion of one or more recombination sites. Since Neylon does not disclose the invention as presently claimed, Applicants respectfully request reconsideration and withdrawal of this rejection.

***VII. The Rejection of Claim 54 Under 35 U.S.C. § 102(b) as Being Anticipated by Perkin Elmer Cetus Must be Withdrawn***

In the Office Action at page 5, section 12, the Examiner rejected claim 54 under 35 U.S.C. § 102(b) as allegedly anticipated by Perkin Elmer Cetus (package insert for the GeneAmp™ Amplification Reagent Kit, shipped October 17, 1988). Applicants respectfully request reconsideration and withdrawal of this rejection.

A claimed invention is anticipated under 35 U.S.C. § 102 only if there is "[d]isclosure in a single piece of prior art of each and every limitation of a claimed

invention." *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 20, 57 USPQ2d 1057, 1061 (Fed. Cir. 2000), *citing Electro Med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052, 32 USPQ2d 1017, 1019 (Fed. Cir. 1994). Applicants respectfully submit Perkin Elmer Cetus does not disclose the invention as presently claimed. Accordingly, this rejection is improper and must be withdrawn.

Claim 54 is drawn to a kit comprising a nucleic acid molecule according to claim 1, and further comprising one or more components selected from a group consisting of one or more Ter-binding protein, one or more nucleotides, one or more DNA polymerases, one or more reverse transcriptases, one or more suitable buffers, one or more primers, one or more recombination proteins, instructions, and one or more terminating agents.

Applicants respectfully submit that Perkin Elmer Cetus does not disclose a nucleic acid molecule according to claim 1, *i.e.*, an isolated nucleic acid molecule engineered to comprise all or a portion of at least one Ter-site and comprising at least one recombination site. Since Perkin Elmer Cetus does not disclose the invention as presently claimed, Applicants respectfully request reconsideration and withdrawal of this rejection.

***VIII. The Rejection of Claims 15 and 16 Under 35 U.S.C. § 103(a) as Being Obvious Over Neylon and Gold et al. Must be Withdrawn***

In the Office Action at pages 5 and 6, section 14, the Examiner rejected claims 15 and 16 under 35 U.S.C. § 103(a) as allegedly obvious over Neylon and Gold *et al.* (US patent no. 6,242,246, hereinafter "Gold"). Applicants respectfully request reconsideration and withdrawal of this rejection.

MPEP 2143.03 reads in pertinent part "[t]o establish *prima facie* obviousness of a

claimed invention, all the claim limitations must be taught or suggested by the prior art." (citing *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)). Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case for the obviousness of the presently claimed invention and respectfully request reconsideration and withdrawal of this rejection as it may be applied to the present claims.

Claims 15 and 16 depend, directly or indirectly, from claim 13. Claim 13 is drawn to a solid support comprising at least one oligonucleotide that comprises all or a portion of a Ter site and all or a portion of one or more recombination sites. Claim 15 recites that the oligonucleotide is capable of forming a stem-loop or hairpin. Claim 16 depends from claim 15 and recites that a duplex portion of a stem-loop or hairpin comprises a Ter-site.

As discussed above with reference to claim 13, Neylon does not disclose a solid support comprising at least one oligonucleotide that comprises all or a portion of a Ter site and all or a portion of one or more recombination sites. Further, Neylon does not suggest such an oligonucleotide. Gold does not remedy the deficiency of Neylon since Gold likewise neither discloses nor suggests oligonucleotides having all or a portion of a Ter-site and all or a portion of one or more recombination sites. Since Neylon and Gold, alone or combined, do not disclose or suggest all of the limitations of the invention as presently claimed, Applicants respectfully submit the Examiner has failed to establish a *prima facie* case for the obviousness of the claimed invention and respectfully request reconsideration and withdrawal of this rejection.

### ***Conclusion***

Applicants respectfully submit that the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will

expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Lawrence J. Carroll". The signature is fluid and cursive, with the first name "Lawrence" and last name "Carroll" clearly distinguishable.

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